



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1992-N-0011]

Sanyasi Raju Kalidindi; Grant of Special Termination

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has issued an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) granting special termination of the debarment of Sanyasi Raju Kalidindi. FDA based the order on a finding that Dr. Kalidindi provided substantial assistance in the investigations or prosecutions of offenses relating to a matter under FDA's jurisdiction and that terminating Dr. Kalidindi's debarment served the interest of justice and protected the integrity of the drug approval process.

DATES: The order became effective September 15, 2021.

ADDRESSES: Comments should reference Docket No. FDA-1992-N-0011 and be sent to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Karena Cooper, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4218, Silver Spring, MD 20993, 301 796-1612.

SUPPLEMENTARY INFORMATION: In a *Federal Register* notice dated April 21, 1993 (58 FR 21470), FDA debarred Dr. Kalidindi from providing services in any capacity to a person with an approved or pending drug product application under section 306(a) of the FD&C Act (21 U.S.C. 335a(a)). FDA based the debarment on a finding under section 306(a)(2) of the FD&C Act that Dr. Kalidindi had been convicted of a felony under Federal law for conduct relating to

the development, or approval, of any drug product or otherwise relating to the regulation of a drug product.

Section 306(d)(4) of the FD&C Act provides that any individual debarred under section 306(a)(2) may apply to FDA for special termination of debarment. Pursuant to section 306(d)(4)(C)-(D), FDA may grant a request for special termination and limit the period of debarment to less than permanent but no less than 1 year if the Agency finds: (1) that the individual has provided substantial assistance in the investigations or prosecutions of offenses described in section 306(a) or (b) of the FD&C Act, or relating to any matter under the jurisdiction of FDA and (2) that doing so best serves the interest of justice and protects the integrity of the drug approval process.

On May 27, 1998, FDA denied a previous petition for special termination of debarment submitted by Dr. Kalidindi. On January 13, 2020, Dr. Kalidindi again petitioned for special termination of debarment under section 306(d)(4) of the FD&C Act. On April 10, 2020, FDA's Office of Regulatory Affairs proposed denying that petition and offered Dr. Kalidindi an opportunity to request a hearing on the proposal to deny the petition. On May 9, 2020, Dr. Kalidindi requested a hearing and, on June 8, 2020, submitted materials in support of his hearing request.

By a decision dated September 15, 2021, FDA's Chief Scientist granted Dr. Kalidindi's petition for special termination based on her conclusion that doing so best served the interest of justice and protected the integrity of the drug approval process. In so concluding, she found that there were no genuine and substantial issues of fact with respect to the level and scope of substantial assistance provided by Dr. Kalidindi in the investigation and prosecution of others for offenses described in section 306(a) or (b) of the FD&C Act, or otherwise relating to FDA's jurisdiction, and that the level and scope of such substantial assistance, among other considerations, justified special termination of his debarment after 28 years. The Chief Scientist's decision is available at <https://www.fda.gov/media/152270/download>. The decision is

also available at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/fda-debarment-list-drug-product-applications/fda-expired-debarment-list-drug-product-applications>.

Dated: November 4, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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